Annual Index

Vol. 9 Nos. 1–12, Jan.–Dec. 1983

Subject Index

A

Acute myocarditis
Toxoplasmosis: a cause of myocarditis (David Leak, MB) Feb, 9:149

Advanced life support
Prehospital coronary care: does it save lives? (Richard P. Lewis, MD) Jun, 9:91

A.I.D.S.
A.I.D.S.: a 20th-century plague (Louis M. Aledort, MD) May, 9:15

American College of Cardiology
Controversies in cardiology Aug, 9:180
A special report from the 32nd annual scientific session of the ACC, Aug, 9:175

American Heart Association
Special report from the 55th scientific sessions Mar, 9:205

Angina pectoris
Angina pectoris: advances in medical therapy (Robert Zelis, MD, and Stephen F. Flaim, MD) Feb, 9:107
Identifying the high-risk unstable angina patient: Holter monitoring (Stacey M. Johnson, MD) Mar, 9:89
Stable angina pectoris: use of diltiazem (William E. Strauss, MD) Aug, 9:33
The underestimation of nitroglycerin and long-acting nitrates (Jonathan Abrams, MD) Feb, 9:8
Variant and exertional angina: role of coronary tone (Stephano de Servi, MD, et al) Apr, 9:71

Antiarrhythmics
Disopyramide: an update (Frank Morady, MD) Oct, 9:18

Aortic insufficiency
Aortic regurgitation (Jonathan Abrams, MD) part I, Apr, 9:16; part II, May, 9:16
Aortic stenosis (Jonathan Abrams, MD) Mar, 9:28
A forgotten case of aortic incompetence? (Robin J. Northcote, MD, ChB, MRCP, and David Ballantyne, MD, FRCP) Jul, 9:151

Arrhythmias
Aggravation of arrhythmias: a potential complication of therapy (Philip J. Podrid, MD) Jul, 9:75
Arrhythmias caused by "antiarrhythmic" drugs (Joel Kupersmith, MD) Jul, 9:12
Malignant ventricular arrhythmia: noninvasive aids to management (Thomas B. Graboys, MD) Sep, 9:15
Ventricular arrhythmias: prognostic importance in coronary disease (Robert M. Califf, MD, David B. Pryor, MD, Frank E. Harrell, MD) Nov, 9:146

Atrial septal defect
A suspicious hilar mass (Martin N. Cohen, MD) Feb, 9:48

Primary Cardiology—Disc 68
File: p218aa01; Article: Annual Index/Subject
12/16/83 (djr) 2nd galley

B

Beta-blocking agents
Prevention of reinfarction: use of beta blockers (Stanley H. Taylor, MD) Nov, 9:89
Treatment of hypertension: use of pindolol (John B. Kostis, MD and Michael C. Ruddy, MD) Sep, 9:53

Blood pressure
Blood pressure in young men: prediction and prognosis (Simon W. Rabkin, MD) Jan, 9:205

Book reviews
May, 9:52

Bradycardia
Bradycardia: in children and young adults (Paul C. Gillette, MD) Apr, 9:163

C

Calcium antagonists
Coronary spasm: uses of nefidipine and isosorbide dinitrate (James A. Hill, MD, and C. Richard Conti, MD) May 9:104
Hypertension treatment: use of calcium blockers (John P. Nicholson, Jr., MD, and David B. Case, MD) Jul, 9:108
Stable angina pectoris: use of diltiazem (William E. Strauss, MD) Aug, 9:33

Cardiomyopathy
Alcoholic cardiomyopathy (J.T. Lie, MD) Mar, 9:179
Hypertrophic cardiomyopathy (William J. McKenna, MD) Jun, 9:69

Chest pain
Almost typical chest pain (Martin N. Cohen, MD, et al) Feb, 9:42
An unusual cause of dyspnea, weight loss, and chest pain (Mel Clark, MD, Gary Worcester, MD, and Udho Thadani, MBBS) Aug, 9:56
Atypical left chest pain (Martin N. Cohen, MD) Jan 9:63
Periodic chest pain: documenting myocardial ischemia, part II (Leonard G. Christie, Jr., MD, and C. Richard Conti, MD) Jan, 9:163

Clinical cardiology
Computed tomography: a new view of cardiovascular disease (Bruce H. Brundage, MD) Jul, 9:57
Heart-muscle disease: the biomechanics of congestive heart failure (Niki E. Kantrowitz, MD, and Michael R. Bristow, MD, PhD) Jun 9:116

Clinical horizons

American College of Cardiology
A special report from the 32nd annual scientific session of the ACC, Aug, 9:175

American Heart Association
Special report from the 55th scientific sessions Mar, 9:205

Angiography
digital subtraction angiography Sep, 9:176

Arrhythmias
associated with snoring Jun, 9:183

Beta blockade
beta-blocker safety Jan, 9:174
propranolol and subarachnoid hemorrhage Jan, 9:174

Cardiac rehabilitation update 1983
aggressive training recommended Oct, 9:45
home exercise conditioning Oct, 9:119
patient and spouse groups Oct, 9:121
Pritikin diet more effective than exercise Oct, 9:119
voluntary discharge benefits patient Oct, 9:85

Congestive heart disease
reduction of CHD incidence Nov, 9:33

Diuretics
too much may cause problem Nov, 9:33

FDA approval
alpha-agonist Jan, 9:175

Fetal heart monitoring
can be done at home Nov, 9:36

Annual Index

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Subject Index

A

Acute myocarditis
Toxoplasmosis: a cause of myocarditis (David Leak, MB) Feb, 9:149

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A.I.D.S.: a 20th-century plague (Louis M. Aledort, MD) May, 9:15

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Controversies in cardiology Aug, 9:180
A special report from the 32nd annual scientific session of the ACC, Aug, 9:175

American Heart Association
Special report from the 55th scientific sessions Mar, 9:205

Angina pectoris
Angina pectoris: advances in medical therapy (Robert Zelis, MD, and Stephen F. Flaim, MD) Feb, 9:107
Identifying the high-risk unstable angina patient: Holter monitoring (Stacey M. Johnson, MD) Mar, 9:89
Stable angina pectoris: use of diltiazem (William E. Strauss, MD) Aug, 9:33
The underestimation of nitroglycerin and long-acting nitrates (Jonathan Abrams, MD) Feb, 9:8
Variant and exertional angina: role of coronary tone (Stephano de Servi, MD, et al) Apr, 9:71

Antiarrhythmics
Disopyramide: an update (Frank Morady, MD) Oct, 9:18

Aortic insufficiency
Aortic regurgitation (Jonathan Abrams, MD) part I, Apr, 9:16; part II, May, 9:16
Aortic stenosis (Jonathan Abrams, MD) Mar, 9:28
A forgotten case of aortic incompetence? (Robin J. Northcote, MD, ChB, MRCP, and David Ballantyne, MD, FRCP) Jul, 9:151

Arrhythmias
Aggravation of arrhythmias: a potential complication of therapy (Philip J. Podrid, MD) Jul, 9:75
Arrhythmias caused by "antiarrhythmic" drugs (Joel Kupersmith, MD) Jul, 9:12
Malignant ventricular arrhythmia: noninvasive aids to management (Thomas B. Graboys, MD) Sep, 9:15
Ventricular arrhythmias: prognostic importance in coronary disease (Robert M. Califf, MD, David B. Pryor, MD, Frank E. Harrell, MD) Nov, 9:146

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A suspicious hilar mass (Martin N. Cohen, MD) Feb, 9:48

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B

Beta-blocking agents
Prevention of reinfarction: use of beta blockers (Stanley H. Taylor, MD) Nov, 9:89
Treatment of hypertension: use of pindolol (John B. Kostis, MD and Michael C. Ruddy, MD) Sep, 9:53

Blood pressure
Blood pressure in young men: prediction and prognosis (Simon W. Rabkin, MD) Jan, 9:205

Book reviews
May, 9:52

Bradycardia
Bradycardia: in children and young adults (Paul C. Gillette, MD) Apr, 9:163

C

Calcium antagonists
Coronary spasm: uses of nefidipine and isosorbide dinitrate (James A. Hill, MD, and C. Richard Conti, MD) May 9:104
Hypertension treatment: use of calcium blockers (John P. Nicholson, Jr., MD, and David B. Case, MD) Jul, 9:108
Stable angina pectoris: use of diltiazem (William E. Strauss, MD) Aug, 9:33

Cardiomyopathy
Alcoholic cardiomyopathy (J.T. Lie, MD) Mar, 9:179
Hypertrophic cardiomyopathy (William J. McKenna, MD) Jun, 9:69

Chest pain
Almost typical chest pain (Martin N. Cohen, MD, et al) Feb, 9:42
An unusual cause of dyspnea, weight loss, and chest pain (Mel Clark, MD, Gary Worcester, MD, and Udho Thadani, MBBS) Aug, 9:56
Atypical left chest pain (Martin N. Cohen, MD) Jan 9:63
Periodic chest pain: documenting myocardial ischemia, part II (Leonard G. Christie, Jr., MD, and C. Richard Conti, MD) Jan, 9:163

Clinical cardiology
Computed tomography: a new view of cardiovascular disease (Bruce H. Brundage, MD) Jul, 9:57
Heart-muscle disease: the biomechanics of congestive heart failure (Niki E. Kantrowitz, MD, and Michael R. Bristow, MD, PhD) Jun 9:116

Clinical horizons

American College of Cardiology
A special report from the 32nd annual scientific session of the ACC, Aug, 9:175

American Heart Association
Special report from the 55th scientific sessions Mar, 9:205

Angiography
digital subtraction angiography Sep, 9:176

Arrhythmias
associated with snoring Jun, 9:183

Beta blockade
beta-blocker safety Jan, 9:174
propranolol and subarachnoid hemorrhage Jan, 9:174

Cardiac rehabilitation update 1983
aggressive training recommended Oct, 9:45
home exercise conditioning Oct, 9:119
patient and spouse groups Oct, 9:121
Pritikin diet more effective than exercise Oct, 9:119
voluntary discharge benefits patient Oct, 9:85

Congestive heart disease
reduction of CHD incidence Nov, 9:33

Diuretics
too much may cause problem Nov, 9:33

FDA approval
alpha-agonist Jan, 9:175

Fetal heart monitoring
can be done at home Nov, 9:36

Heart disease
"type A" personality Jun, 9:183

Hypertension
alpha-agonist approved Jan, 9:175

Prostaglandins
Special report: the international conference on prostaglandins part I, Apr, 9:151; part II, May, 9:222

Clinical interface (Martin N. Cohen, MD)
Abdominal pain (with Lori Rubin, MD, and Michael Gold, MD) Jun, 9:61
Almost typical chest pain (with David Chess, MD, Chris Comfort, MD, and Alan Bier, MD) Feb, 9:42
Atypical left chest pain Jan, 9:63
Cardiac manifestations of relapsing polychondritis (with Christine E. Lawless, MD, and Patrick J. Scanlon, MD) Nov, 9:56
Cardiomegaly of undetermined cause (Lawrence P. Temkin, MD, and Rubin Bressler, MD) Dec, 9:17
Chest pain and localized ECG changes in a 19-year-old student (Michael G. Seneff, MD, and Joseph S. Alpert, MD) Dec, 9:25
Congestive heart failure following upper respiratory infection (with Arthur H. Meltzer, MD, et al) Nov, 9:41
Congestive heart failure, murmurs, and arthralgias May, 9:145
Coronary insufficiency precipitated by hyperthyroidism Mar, 9:54
Fever and pleural effusion after acute MI May, 9:161
Hemoptysis associated with congestive heart failure Aug, 9:49
Hypertensive heart disease and shortness of breath Jan, 9:57
Shortness of breath and gastrointestinal bleeding Apr, 9:128
Shortness of breath in a patient with Starr-Edwards valve (Kenneth Ellenbogen, MD) Dec, 9:34
Sudden aphasia and hemiparesis Apr, 9:137
A suspicious hilar mass Feb, 9:48
Syncope and bundle branch disease (with Roland Belluscio, MD, and Emanuel Goldberg, MD) Jun, 9:41
An unusual case of back pain (with Kenneth Ellenbogen, MD) Sep, 9:147
An unusual cause of dyspnea, weight loss, and chest pain (with Mel Clark, MD, Gary Worcester, MD, and Udho Thadani, MBBS) Aug, 9:56

Clinical trials
Overinterpretation or misinterpretation of clinical trials (Marvin Moser, MD) Sep, 9:10

Computed tomography
Computed tomography: a new view of cardiovascular disease (Bruce H. Brundage, MD) Jul, 9:57

Computing physician, the (Robert L. Perry and Paul J. Rosch, MD)
Jan, 9:22; Feb, 9:35; Mar, 9:21; Apr, 9:156; May, 9:193; Jun, 9:163; Jul, 9:184; Aug, 9:143; Sep, 9:28; Oct, 9:173; Nov, 9:172; Dec, 9:117

Congestive heart disease
Abdominal pain (Lori Rubin, MD, Michael Gold, MD, and Martin N. Cohen, MD) Jun, 9:61
Congestive heart failure following upper respiratory infection (Arthur H. Meltzer, MD, et al) Nov, 9:41
Heart-muscle disease: the biomechanics of congestive heart failure (Niki E. Kantrowitz, MD, and Michael R. Bristow, MD, PhD) Jun, 9:116
Hemoptysis associated with congestive heart failure Aug, 9:49
Renal failure and congestive heart failure (Marcus Reidenberg, MD) Dec, 9:97

Nitro-Dur®
(nitroglycerin)
Transdermal Infusion System

KEY PHARMACEUTICALS, INC.
Miami, Florida 33269-0670
World leader in
drug delivery systems.

Nitro-Dur®
(nitroglycerin)
Transdermal Infusion System

DESCRIPTION: The Nitro-Dur Transdermal Infusion System contains nitroglycerin in a gel-like matrix composed of glycerin, water (purified), lactose, polyvinyl alcohol, povidone and sodium citrate to provide a continuous source of the active ingredient. Nitro-Dur is available in dosage sizes 5cm², 10cm², 15cm² and 20cm², containing 26 mg, 51 mg, 77 mg and 104 mg of nitroglycerin, respectively, thereby providing a range of dosing levels of nitroglycerin. Nitro-Dur has a rated release in vivo of approximately 0.5mg/cm²/24 hours. Each unit is sealed in a polyester-foil-polyethylene laminate. The bandage portion consists of a medical grade non-woven, heat sealable, microporous tape.

CLINICAL PHARMACOLOGY: When the Nitro-Dur system is applied to the skin, nitroglycerin is absorbed continuously through the skin into the systemic circulation. This results in active drug reaching the target organs (heart, extremities) before deactivation by the liver. Nitroglycerin is a smooth muscle relaxant with vascular effects manifested predominantly by venous dilation and pooling. The major beneficial effect of nitroglycerin in angina pectoris is a reduction in myocardial oxygen consumption secondary to vascular smooth muscle relaxation with resultant reduction in cardiac preload and afterload. In recent years there has been an increasing recognition of a direct vasodilator effect of nitroglycerin on the coronary vessels.

In bioavailability studies using healthy volunteers,[1] transdermal absorption of nitroglycerin from Nitro-Dur achieved steady state venous plasma levels comparable to that of sublingual nitroglycerin and maintained these levels for 24 hours. Detectable plasma levels were attained within 30 minutes after application of the unit, and were still detectable 30 minutes after removal of the unit.

INDICATIONS AND USAGE: This drug product has been conditionally approved by the FDA for the prevention and treatment of angina pectoris due to coronary artery disease. The conditional approval reflects a determination that the drug may be marketed while further investigation of its effectiveness is undertaken. A final evaluation of the effectiveness of the product will be announced by the FDA.

CONTRAINDICATIONS: Intolerance of organic nitrate drugs, marked anemia, increased intraocular pressure or increased intracranial pressure.

WARNINGS: The Nitro-Dur system should be used under careful clinical and/or hemodynamic monitoring in patients with acute myocardial infarction or congestive heart failure.

In terminating treatment of angina patients, both the dosage and frequency of application must be gradually reduced over a period of 4 to 6 weeks in order to prevent sudden withdrawal reactions, which are characteristic of all vasodilators in the nitroglycerin class.

PRECAUTIONS: Symptoms of hypotension, such as faintness, weakness or dizziness, particularly orthostatic hypotension, may be due to overdosage. If during the course of treatment these symptoms occur, the dosage should be reduced or use of the product discontinued.

Nitro-Dur is not intended for use in the treatment of acute anginal attacks. For this purpose, occasional use of sublingual nitroglycerin may be necessary.

ADVERSE REACTIONS: Transient headache is the most common side effect, especially when higher doses of the drug are administered. Headaches should be treated with mild analgesics while continuing Nitro-Dur therapy. If headache persists, the Nitro-Dur dosage should be reduced.

Adverse reactions reported less frequently include hypotension, increased heart rate, faintness, flushing, dizziness, nausea, vomiting, and dermatitis. Except for dermatitis, these symptoms are attributed to the pharmacologic effects of nitroglycerin. However, they may be symptoms of overdosage. When they persist, the Nitro-Dur dosage should be reduced or use of the product discontinued.

HOW SUPPLIED: Nitro-Dur Transdermal Infusion System, 5cm², 10cm², 15cm² and 20cm², is available in unit dose packages of 28 and hospital packs of 100.

CAUTION: Federal law prohibits dispensing without prescription.

PATIENT INSTRUCTIONS FOR APPLICATION: Patient instructions are furnished with each unit dose package.

For complete prescribing information, please see package insert.

[1]Data on file: Key Pharmaceuticals, Inc. 07/83

KEY PHARMACEUTICALS, INC.
Miami, Florida 33269-0670
World leader in drug delivery systems.

ND-1280R

Annual Index

Coronary artery ectasia
Coronary artery ectasia (Demetrios Kimbiris, MD, et al) Aug, 9:152

Coronary artery spasm
The CCU and coronary artery disease mortality (Lee Goldman, MD) Apr, 9:84

Coronary bypass
How many bypass grafts? (Gerald M. Lawrie, MD, and George C. Morris, Jr., MD) Sep, 9:87
The symptomatic patient after coronary bypass (Richard O. Russell, Jr., MD, Nicholas T. Kouchoukos, MD, Charles E. Rackley, MD) Jun, 9:14

D

Death
The CCU and coronary artery disease mortality (Lee Goldman, MD) Apr, 9:84
Death rates of cardiac patients: effects of physical activity (John Naughton, MD) Mar, 9:77

Death, sudden
Persistent risk of sudden death: ventricular arrhythmia in MI survivors (William Ruberman, MD, and Eve Weinblatt, AB) Jan, 9:33
Preventing sudden cardiac death (Neil M. Sokoloff, MD, Leonard N. Horowitz, MD, and Joel Morganroth, MD) Aug, 9:77

Deep-vein thrombosis
Suspected venous thrombosis: validity of a negative venogram (RD Hull, MD) Apr, 9:29
Venous thrombosis of the legs: noninvasive diagnostic techniques (John J. Cranley, MD, and Eugene D. Sullivan, MD) Aug, 9:16

Diagnostic tips
aortoduodenal fistula Oct, 9:170
aspirin-induced asthma Dec, 9:16
brittle diabetes and propranolol Jun, 9:166
clues to right ventricular MI Aug, 9:151
inferior wall MI Dec, 9:16
propranolol and alopecia Nov, 9:2
pulmonary embolism Nov, 9:2
quinidine-induced syncope Jun, 9:166
ventricular aneurysm Oct, 9:170

Digitalis
Acute and chronic heart failure: use of digitalis (Kanu Chatterjee, MD, and William W. Parmley, MD) Jan, 9:139

Digoxin
Digoxin-drug interactions (Mitchell Wolfson, MD, and Joel Kupersmith, MD) Nov, 9:50
Verapamil-digoxin interaction: an update (Herman O. Klein, MD, Roberto Lang, MD, and Elieser Kaplinsky, MD) Sep, 9:105

Diuretics
Drug interactions with thiazide diuretics (Ted S. Friedman, MSc, RPh and Bernard Mehl, DPS) Nov, 9:165
too much may cause problem Nov, 9:33

Dysrhythmias
Dysrhythmias in pediatric patients: use of verapamil (Co-burn J. Porter, MD, Arthur Garson, Jr., MD, and Paul Gillette, MD) May, 9:31

E

ECG of the month (Edward K. Chung, MD)
Atrial fibrillation Nov, 9:26
Atrial flutter Dec, 9:90
Broad QRS complexes Oct, 9:135
Escape beats and rhythms of different origins May, 9:97
Myocardial infarction: various locations Mar, 9:198

Poor progression of R wave Jan, 9:92
Prolongation of QT interval Jun, 9:109
Regular irregularity of the atrial cycle Sep, 9:46
Regular irregularity of the ventricular cycle Aug, 9:164
Regular ventricular cycle Jul, 9:133
Right ventricular hypertrophy Feb, 9:99
Wandering atrial pacemaker Apr, 9:40

Echocardiography
Acute myocardial infarction: immediate diagnosis with two-dimensional echocardiography (Joel Morganroth, MD) May, 9:71
Carcinoid heart disease: diagnostic usefulness of echocardiography (Jack M. Gutman, MD, BS, and Nelson B. Schiller, MD) Feb, 9:130
Echocardiography in hemodialysis (Michel Chaignon, MD, and Jacques Guedon, MD) Nov, 9:69
Introduction to cross-sectional echocardiography (Martin E. Goldman, MD) Jul 9:40
Left ventricular filling pressure: noninvasive measurement (Joseph Ashkenazi, MD, and Michael Lesch, MD) Oct, 9:31

Edema
Intractable edema: new treatments—and old (J. Pedro Frommer, MD, and Neil A. Kurtzman, MD) Dec, 9:81

Editorial/Editors' page
Acute myocardial infarction: use of cardiac glycosides (Richard Gorlin, MD) Jun, 9:12
A.I.D.S.: A 20th-Century Plague (Louis M. Aledort) May, 9:15
Arrhythmias caused by "antiarrhythmic" drugs (Joel Kupersmith, MD) Jul, 9:12
The debate continues: what to do about mild hypertension (Marvin Moser, MD, and Ray Gifford, MD) Apr, 9:14
Drug-related sexual dysfunction (Norman M. Kaplan, MD) Mar, 9:15
Exercise and cardiovascular disease (Clarence M. Agress, MD) Oct, 9:12
Orphan drugs (Theodore Cooper, MD, PhD) Aug, 9:13
Overinterpretation or misinterpretation of clinical trials (Marvin Moser, MD) Sep, 9:10
Preventive intervention in coronary artery disease (Arthur Selzer, MD) Jan, 9:14
The underestimation of nitroglycerin and long-acting nitrates (Jonathan Abrams, MD) Feb, 9:8
What have we wrought? (Marvin Moser, MD) Dec, 9:9

Emergency pointers
air embolism May, 9:221
artifact as v-fib Jan, 9:190
beta blockers and I.V. verapamil Feb, 9:194
BP elevation and hypoxemia May, 9:221
Chagas' disease Nov, 9:84
chronic obstructive pulmonary disease Jan, 9:190
cough syncope Apr, 9:168
c-spine stabilization Jan, 9:190
diagnosing accident victims Oct, 9:172
esophageal obturator airway Feb, 9:194
hypertensive crisis and carbazine Apr, 9:188
lab findings and MIs Mar, 9:52
lupus anticoagulant Dec, 9:80
massive hemothorax Feb, 9:194
nonbacterial thrombotic endocarditis Aug, 9:119; Nov, 9:84
organic brain syndrome with nadolol Mar, 9:204
pneumothorax masquerading as MI May, 9:221
superior vena cava syndrome Jun, 9:37
traumatic aortic rupture Nov, 9:84
traumatic asphyxia Jun, 9:37

Exercise
Athlete's heart: normality, abnormality, supernormality (G.D.G. Oakley, MRCP) Nov, 9:126
Coronary heart disease: benefits of exercise training (Ali A. Ehsani, MD) Jul, 9:125
Death rates of cardiac patients: effects of physical activity (John Naughton, MD) Mar, 9:77
Modifications of coronary risk: the benefits of exercise (Kenneth K. Wenger, MD) Nov, 9:114
Variant and exertional angina: role of coronary tone (Stephano de Servi, MD, et al) Apr, 9:71

Exercise testing
Early positive exercise test: implications for prognosis (Ricky M. Schneider, MD, John F. Seaworth, MD, and John T. Baker, MD) Dec, 9:49
Exercise testing after acute myocardial infarction (Francis M. Weld, MD, and William E. DeTurk, MD) Jan, 9:116
Exercise testing for children (Diane Goforth, MD, and Frederick W. James, MD) Aug, 9:182
Exercise testing in perspective (Peter H. Stone, MD) Mar, 9:111
Variant and exertional angina: role of coronary tone (Stephano de Servi, MD, et al) Apr, 9:71

H

Heart disease
Carcinoid heart disease: diagnostic usefulness of echocardiography (Jack M. Gutman, MB, BS, and Nelson B. Schiller, MD) Feb, 9:130
Cardiovascular disease in the elderly (William B. Kannel, MD) May, 9:206
Coronary heart disease: benefits of exercise training (Ali A. Ehsani, MD) Jul, 9:125
Infective endocarditis: when to operate (Mark J. DiNubile, MD) Dec, 9:105
Systemic lupus erythematosus and heart disease (Richard R. Liberthson, MD, et al) Jan, 9:77

Heart failure
Acute and chronic heart failure: use of digitalis (Kanu Chatterjee, MB, and William W. Parmley, MD) Jan, 9:139
Mitral annular calcification: changing concepts (Chandra K. Nair and Thomas Pagano, MD) Dec, 9:57

Hemiparesis
Febrile patient with hemiparesis and aphasia (C. Glenn Cobbs, MD, and George H. Karam, MD) Jul, 9:142
Sudden aphasia and hemiparesis (Martin N. Cohen, MD) Apr, 9:137

Hemodynamic monitoring
Hemodynamic monitoring in acute cardiac illness (Abdulmassih S. Iskandrian, MD, A-Hamid Hakki, MD, and Bernard L. Segal, MD) Aug, 9:92

Holter monitoring
Identifying the high-risk unstable angina patient: Holter monitoring (Stacey M. Johnson, MD) Mar, 9:89

Hypertension
The debate continues: what to do about mild hypertension (Marvin Moser, MD, and Ray Gifford, MD) Apr, 9:14
Hypertension treatment: use of calcium blockers (John P. Nicholson, Jr., MD and David B. Case, MD) Jul, 9:108
Hypokalemia: real and potential hazards (Norman M. Kaplan, MD) May, 9:133
"Mild" hypertension: risks and strategy for control (Rose Stamler, MA, and Jeremiah Stamler, MD), part I, Oct, 9:150; part II, Nov, 9:12
Treatment of hypertension: use of pindolol (John B. Kostis, MD, and Michael C. Ruddy, MD) Sep, 9:53

Hypertension outlook
Alcohol
hypertension role needs clarification Jun, 9:36

Essential
mechanisms discussed Jun, 9:34

Sodium intake
perception of saltiness Jun, 9:34

sodium reduction affects intake of essential nutrients Jan, 9:34

Symposium
hypertension definition offered Jan, 9:34

Hyperventilation
Hyperventilation: a diagnostic dilemma (James V. Warren, MD) Sep, 9:127
Pseudoischemic ST-segment changes induced by hyperventilation (Carl L. Tommaso, MD, and Julius M. Gardin, MD) Apr, 9:111

I

Ischemia
Coronary spasm: uses of nifedipine and isosorbide dinitrate (James A. Hill, MD, and C. Richard Conti, MD) May, 9:104
Pseudoischemic ST-segment changes induced by hyperventilation (Carl L. Tommaso, MD, and Julius M. Gardin, MD) Apr, 9:111
Ventricular tachycardia in acute, subacute, and chronic ischemic heart disease (J. Thomas Bigger, Jr, MD) May, 9:55

L

Left ventricle
Left ventricular filling pressure: noninvasive measurement (Joseph Askenazi, MD, and Michael Lesch, MD) Oct, 9:31
Left ventricular size and performance: noninvasive assessment (Michael H. Crawford, MD) Feb, 9:115
Left ventricular thrombosis after myocardial infarction (Richard W. Asinger, MD, and Frank L. Mikell, MD) Feb, 9:19

M

Mitral annulus calcification
Mitral annular calcification: changing concepts (Chandra K. Nair, MD, and Thomas Pagano, MD) Dec, 9: 57
Mitral annulus calcification: complications (Ivan D'Cruz, MD) May, 9:114

Mitral stenosis
Detecting mitral stenosis (Jonathan Abrams, MD) Jun, 9:141

Mitral valve prolapse
Abdominal pain (Lori Rubin, MD, Michael Gold, MD, and Martin N. Cohen, MD) Jun, 9:61
Hyperthyroidism or mitral valve prolapse (Barry Denenberg, MD, Bertram J. Channick, MD, and James F. Spann, MD) Oct, 9:73
Mitral regurgitation: how to recognize (Jonathan Abrams, MD) Oct, 9:98

Myocardial infarction
Acute myocardial infarction: evaluation with radionuclide ventriculography (C. Fagg Sanford, MD) Oct, 9:121
Acute myocardial infarction: immediate diagnosis with two-dimensional echocardiography (Joel Morganroth, MD) May, 9:71

Acute myocardial infarction: use of cardiac glycosides (Richard Gorlin, MD) Jun, 9:12
Anterior inferior myocardial infarction: precordial ST-segment depression (P.K. Shah, MD, et al) Jul, 9:173
Exercise testing after acute myocardial infarction (Francis M. Weld, MD, and William E. DeTurk, MD) Jan, 9:116
Left ventricular thrombosis after myocardial infarction (Richard W. Asinger, MD, and Frank L. Mikell, MD) Feb, 9:19
Myocardial infarction injury score (Pentti M. Rautaharju, MD) Jun, 9:171
Myocardial infarction: various locations (Edward K. Chung, MD) Mar, 9:198
Post-MI syndrome: incidence and clinical presentation (Edgar Lichstein, MD) Sep, 9:172
Prevention of reinfarction: use of beta blockers (Stanley H. Taylor, MD) Nov, 9:89
Psychological distress: risk factor for acute MI (John E. Madias, MD) Oct, 9:141
Systemic lupus erythematosus and heart disease (Richard R. Liberthson, MD, et al) Jan, 9:77

N

Nitrates
Coronary spasm: uses of nifedipine and isosorbide dinitrate (James A. Hill, MD, and C. Richard Conti, MD) May, 9:104
The underestimation of nitroglycerin and long-acting nitrates (Jonathan Abrams, MD) Feb, 9:8

O

"Orphan drugs"
Orphan drugs (Theodore Cooper, MD, PhD) Aug, 9:13

P

Pacemakers
Problems in pacemaker ECG interpretation (Robert B. Leman, MD, and Peter C. Gazes, MD), part I, Aug, 9:120; part II, Sep, 9:77

Patent ductus arteriosus
Patent ductus arteriosus (Welton M. Gersony, MD) Jun, 9:26

Physical diagnosis
Aortic regurgitation (Jonathan Abrams, MD), part I, Apr, 9:16; part II, May, 9:16
Detecting mitral stenosis (Jonathan Abrams, MD) Jun, 9:141

Potassium
Hypokalemia: real and potential hazards (Norman M. Kaplan), May, 9:133

Primary care reporter

Allergy
asthma linked to caffeine Aug, 9:72
MSG linked to asthma Aug, 9:72

Cardiology
calcium blockers in angina Mar, 9:66
captopril in hypertension Mar, 9:63
cardiac rehabilitation Sep, 9:163
digitalis use Feb, 9:76
exercise in the elderly Jan, 9:69
managing unstable angina Aug, 9:66
post-MI exercise Jan, 9:69
relaxation response Sep, 9:166

Dermatology
atopic dermatitis Sep, 9:171
obstructive jaundice Nov, 9:62

Endocrinology
CS II systems in type I diabetes Aug, 9:67
hypothyroidism and hypertension Jul, 9:169
identifying thyroiditis Dec, 9:42
insulin overtreatment Aug, 9:70

Gastroenterology
diarrhea and proctocolitis Jul, 9:159
dissolving gallstones Mar, 9:68
new drug treatment for gallstones, Dec, 9:42
therapeutic endoscopy Mar, 9:68

Hematology
aspirin and thromboxane production Apr, 9:150

Immunology
insect venom therapy Aug, 9:63

Infectious disease
acyclovir for herpes simplex and Epstein-Barr infections May, 9:152
AIDS: immunologic profile Aug, 9:67
antifungal agents Apr, 9:142
contaminated marijuana Feb, 9:80
H. flu resistance Feb, 9:79
ketoconazole assessed Mar, 9:68
MI and viral infections Feb, 9:80
moxalactam in non-CNS infections Feb, 9:79
N. meningitis guidelines Jan, 9:76

Nutrition
diagnosing deficiencies Jun, 9:60

Obstetrics/gynecology
C. trachomatis in black women Jan, 9:75
ketoconazole and candidiasis Jan, 9:70
LRF counteracts OCs Feb, 9:78
misdiagnosis of C. acuminatum Jan, 9:75
pulsatile GnRH Feb, 9:78
sexual problems Feb, 9:75
teratogenicity of ketoconazole Jan, 9:70

Oncology
chemotherapy for testicular cancer Dec, 9:42
drug therapy for Kaposi's carcinoma Nov, 9:62
early breast cancer treatment Nov, 9:62
human T-lymphoma virus Mar, 9:73
multimodal treatment for cancer pain Sep, 9:170
office diagnosis of endometrial cancer Mar, 9:160

Ophthalmology
laser therapy Mar, 9:73
racquet sports injuries Jun, 9:164

Pediatrics
early diagnosis of hypertension Jun, 9:53

Psychiatry
sleep disorders Jul, 9:169

Pulmonary medicine
asthma control with beclomethasone Jun, 9:56
malnutrition and COPD Jul, 9:161

Rheumatology
arthritis drug therapy May, 9:153
chronic low back pain Jan, 9:68
clinical rheumatology Jan, 9:67
diet and arthritis Mar, 9:72
SLE criteria Mar, 9:69

Sports medicine
on-the-spot management of sports injuries Sept, 9:171

Urology
bladder training regimen Sep, 9:167
impotence and arterial insufficiency Apr, 9:147
shifting patterns of STDs Sep, 9:167
stress and prostatitis Apr, 9:147

Vascular disease
prostacyclin in Raynaud's syndrome Jul, 9:181

Pulmonary edema
Unilateral pulmonary edema (Dan Tzivoni, MD, Andre Keren, MD, and Shlomo Stern, MD) Mar, 9:163

Pulmonary vascular disease
Pulmonary vascular disease with congenital heart lesions (Julien I.E. Hoffman, MD) May, 9:169

R

Right ventricular infarction
ECG of the month (Edward K. Chung, MD) Feb, 9:99
Right ventricular infarction: changing concepts (Charles E. Croft, MD, Robert E. Rude, MD, and James T. Willerson, MD) Jul, 9:21

S

Sexual dysfunction
Drug-related sexual dysfunction (Norman M. Kaplan, MD) Mar, 9:15

Sick sinus syndrome
Sick sinus syndrome in young adults (Richard H. Kay, MD and Isaac Wiener, MD) Jun, 9:129

Surgery
Infective endocarditis: when to operate (Mark J. DiNubile, MD) Dec, 9:105
Noncardiac surgery and dentistry in cardiac patients (Peter C. Gazes, MD), part I, Feb, 9:52; part II, Mar, 9:139
Surgery for post-MI complications (Lawrence H. Cohn, MD) May, 9:84

Systemic diseases
Alcoholic cardiomyopathy (J.T. Lie, MD) Mar, 9:179

T

Thyrotoxicosis
Thyrotoxicosis and the heart (Michael V. Cohen, MD) Apr, 9:95

V

Venous stasis
Varicose veins and venous stasis of the legs (Malcolm O. Perry, MD) Jul, 9:88

Verapamil
Verapamil-digoxin interaction: an update (Herman O. Klein, MD, Roberto Lang, MD, Elieser Kaplinsky, MD) Sep, 9:105

Continued on page 147

Annual Index Vol. 9 Nos. 1-12, Jan.-Dec. 1983

Continued from page 142

Author Index

A

Abbott, Robert D., PhD Chronic atrial fibrillation in the general population, Apr, 9:49.

Abrams, Jonathan, MD Aortic stenosis: clues to the three valvar types, Mar, 9:28. Aortic regurgitation, part I, Apr, 9:16; part II, May, 9:16. Detecting mitral stenosis, Jun, 9:141. Mitral regurgitation: how to recognize, Oct, 9:98. The underestimation of nitroglycerin and long-acting nitrates, Feb, 9:8.

Agress, Clarence M., MD Exercise and cardiovascular disease, Oct, 9:12.

Aledort, Louis M., MD A.I.D.S.: a 20th-century plague, May, 9:15.

Alpert, Joseph S., MD Chest pain and localized ECG changes in a 19-year-old student, Dec, 9:25.

Ardissino, Diego, MD Variant and exertional angina: role of coronary tone, Apr, 9:71.

Asinger, Richard W., MD Left ventricular thrombosis after myocardial infarction, Feb, 9:19.

Askenazi, Joseph, MD Left ventricular filling pressure: noninvasive measurement, Oct, 9:31.

B

Baker, John T., MD Early positive exercise test: implications for prognosis, Dec. 9:49.

Ballantyne, David, MD, A forgotten cause of aortic incompetence? Jul, 9:151.

Belluscio, Roland, MD Syncope and bundle branch disease, Jun, 9:41.

Bemis, Charles E., MD Coronary artery ectasia, Aug, 9:152.

Berman, Daniel S., MD Acute inferior myocardial infarction: precordial ST-segment depression, Jul, 9:173.

Bier, Alan, MD Almost typical chest pain, Feb, 9:42.

Bigger, J. Thomas, Jr., MD Controversies in cardiology, Aug, 9:180. Ventricular tachycardia in acute, subacute, and chronic ischemic heart disease, May, 9:55.

Bobba, Piero, MD Variant and exertional angina: role of coronary tone, Apr, 9:71.

Bressler, Rubin, MD Cardiomegaly of undetermined cause, Dec, 9:17.

Bristow, Michael R., MD, PhD Heart-muscle disease: the biomechanics of congestive heart failure, Jun, 9:116.

Brundage, Bruce H., MD Computed tomography: a new view of cardiovascular disease, Jul, 9:57.

C

Califf, Robert H., MD Ventricular arrhythmias: prognostic importance in coronary disease, Nov, 9:146.

Case, David B., MD Hypertension treatment: use of calcium blockers, Jul, 9:108.

Chaignon, Michel, MD Echocardiography in hemodialysis, Nov, 9:69.

Channick, Bertram J., MD Hyperthyroidism or mitral valve prolapse, Oct, 9:73.

Chatterjee, Kanu, MD Acute and chronic heart failure: use of digitalis, Jan, 9:139.

Chess, David, MD Almost typical chest pain, Feb, 9:42.

Christie, Leonard J., Jr., MD Periodic chest pain: documenting myocardial ischemia, part II, Jan, 9:163.

Chung, Edward K., MD ECG of the month: Poor progression of R waves, Jan, 9:92; Right ventricular hypertrophy, Feb, 9:99; Myocardial infarction at different sites, Mar, 9:198; Wandering atrial pacemaker, Apr, 9:40; Escape beats and rhythm of different origins, May, 9:97; Prolongation of Q-T interval, Jun, 9:109; Regular ventricular cycle, Jul, 9:133; Regular irregularity of the ventricular cycle, Aug, 9:164; Regular irregularity of the atrial cycle, Sep, 9:46; Broad QRS complexes, Oct, 9:135, Atrial fibrillation, Nov, 9:26; Atrial flutter, Dec, 9:90.

Clark, Mel, MD An unusual case of dyspnea, weight loss, and chest pain, Aug, 9:56.

Cobbs, C. Glenn, MD Febrile patient with hemiparesis and aphasia, Jul, 9:142.

Cohen, Martin N., MD Clinical interface: Hypertensive heart disease and shortness of breath, Jan, 9:57; Atypical left chest pain, Jan, 9:73; Almost typical chest pain, Feb, 9:42; Almost typical chest pain, Feb, 9:48; Coronary insufficiency precipitated by hyperthyroidism, Mar, 9:54; Hemolytic anemia caused by valvular heart disease, Mar, 9:74; Shortness of breath and gastrointestinal bleeding, Apr, 9:128; Sudden aphasia and hemiparesis, Apr, 9:137; Congestive heart failure, murmurs, and arthralgias, May, 9:145; Fever and pleural effusion after myocardial infarction, May, 9:161; Abdominal pain, Jun, 9:61; Clinical interface, Jul, 9:141; 15-hemoptysis associated with congestive heart failure, Aug. 9:49; How to differentiate cardiovascular disorders from other problems of internal medicine, Sep, 9:143; Oct, 9:41; Congestive heart failure following URI, Nov, 9:41; Cardiac manifestations of relapsing polychondritis, Nov, 9:56.

Cohen, Michael V., MD Thyrotoxicosis and the heart, Apr, 9:95.

Cohn, Lawrence H., MD Surgery for post-MI complications, May, 9:84.

Comfort, Chris, MD Almost typical chest pain, Feb, 9:42.

Conti, C. Richard, MD Periodic chest pain: documenting myocardial ischemia, part II, Jan, 9:163. Coronary spasm: uses of nefidipine and isosorbide dinitrate, May, 9:104.

Cooper, Theodore, MD, PhD Orphan drugs, Aug, 9:13.

Cranley, John J., MD Venous thrombosis of the legs: noninvasive diagnostic techniques, Aug, 9:16.

Crawford, Michael H., MD Left ventricular size and performance: noninvasive assessment, Feb, 9:175.

Croft, Charles H., MD Right ventricular infarction: changing concepts, Jul, 9:21.

D

D'Cruz, Ivan A., MD Mitral annulus calcification: complications, May, 9:114.

Denenberg, Barry, MD Hyperthyroidism or mitral valve prolapse, Oct, 9:73.

DeServi, Stefano, MD Variant and exertional angina: role of coronary tone, Apr, 9:71.

DeTurk, William E., RPT, MA Exercise testing after acute myocardial infarction, Jan, 9:116.

DiNubile, Mark J., MD Infective endocarditis: when to operate, Dec, 9:105.

E

Ehsani, Ali A., MD Coronary heart disease: benefits of exercise training, Jul, 9:125.

Ellenbogen, Kenneth, MD An unusual case of back pain, Sep, 9:147. Shortness of breath in a patient with Starr-Edwards valve, Dec, 9:34.

F

Factor, Stephen, MD Congestive heart failure following upper respiratory infection, Nov, 9:41.

Falcone, Colomba, MD Variant and exertional angina: role of coronary tone, Apr, 9:71.

Fallon, John T., MD, PhD Systemic lupus erythematosus and heart disease, Jan, 9:77.

Flaim, Stephen F., MD Angina pectoris: advances in medical therapy, Feb, 9:107.

Flomenberg, Phyllis, MD Hemolytic anemia caused by valvular heart disease, Mar, 9:74.

Friedman, Ted S., MSc, RPh Drug interactions with thiazide diuretics, Nov, 9:165.

Frommer, J. Pedro, MD Intractable edema: new treatments—and old, Dec, 9:81.

G

Gardin, Julius M., MD Electrocardiographic changes induced by hyperventilation, Apr, 9:111.

Garson, Arthur, Jr., MD Dysrhythmias in pediatric patients: use of verapamil, May, 9:31.

Gazes, Peter C., MD Noncardiac surgery and dentistry in cardiac patients, part I, Feb, 9:52; part II, Mar 9:139. Problems in pacemaker ECG interpretation, part I, Aug, 9:120; part II, Sep 9:77.

Gersony, Welton M., MD Patent ductus arteriosus, Jun, 9:26.

Gifford, Ray, MD The debate continues: what to do about mild hypertension? Apr, 9:14.

Gillette, Paul C., MD Bradycardia: in children and young adults, Apr, 9:163. Dysrhythmias in pediatric patients: use of verapamil, May, 9:31.

Goforth, Diane, MD Exercise testing for children, Aug, 9:182.

Gold, Michael, MD Abdominal pain, Jun, 9:61

Goldberg, Emanuel, MD Syncope and bundle branch disease, Jun, 9:41.

Goldman, Lee, MD The CCU and coronary artery disease mortality, Apr, 9:84.

Goldman, Martin E., MD Introduction to cross-sectional echocardiography, Jul, 9:40.

Gorlin, Richard, MD Acute myocardial infarction: use of cardiac glycosides, Jun, 9:12.

Graboys, Thomas B., MD Malignant ventricular arrhythmia: aids to noninvasive management, Sep, 9:15.

Grose, Richard, MD Congestive heart failure following upper respiratory infection, Nov, 9:41.

Gross, Stephen, MD Systemic lupus erythematosus and heart disease, Jan, 9:77.

Guedon, Jacques, MD Echocardiography in hemodialysis, Nov, 9:69.

Gutman, Jack M., MB, BS Carcinoid heart disease: diagnostic usefulness of echocardiography, Feb, 9:130.

H

Hakki, A-Hamid, MD Coronary artery ectasia, Aug, 9:152. Hemodynamic monitoring in acute cardiac illness, Aug, 9:92.

Harrell, Frank E., MD Ventricular arrhythmias: prognostic importance in coronary disease, Nov, 9:146.

Hattori, Vernon, MD Acute inferior myocardial infarction: precordial ST-segment depression, Jul, 9:173.

Hill, James A., MD Coronary spasm: uses of nifedipine and isosorbide dinitrate, May, 9:104.

Hoffman, Julien I.E., MD Pulmonary vascular disease with congenital heart lesions, May, 9:169.

Homcy, Charles, MD Systemic lupus erythematosus and heart disease, Jan, 9:77.

Horowitz, Leonard N., MD Preventing sudden cardiac death, Aug, 9:77.

Hull, R.D., MD Suspected venous thrombosis: validity of a negative venogram, Apr, 9:29.

I

Iskandrian, Abdulmassih S., MD Coronary artery ectasia, Aug, 9:152. Hemodynamic monitoring in acute cardiac illness, Aug, 9:92.

J

James, Frederick W., MD Exercise testing for children, Aug, 9:182.

Johnson, Stacey M., MD Identifying the high-risk unstable angina pectoris patients: Holter monitoring, Mar, 9:89.

K

Kannel, William B., MD Cardiovascular diseases in the elderly, May, 9:206. Chronic atrial fibrillation in the general population, Apr, 9:49.

Kantrowitz, Niki E., MD Heart-muscle disease: the biomechanics of congestive heart failure, Jun, 9:116.

Kaplan, Norman M., MD Hypokalemia: real and potential hazards, May, 9:133. Drug-induced sexual dysfunction, Mar, 9:15.

Kaplinsky, Elieser, MD Verapamil-digoxin interaction: an update, Sep, 9:105.

Karam, George H., MD Febrile patient with hemiparesis and aphasia, Jul, 9:142.

Kay, Richard H., MD Sick sinus syndrome in young adults, Jun, 9:129.

Keefe, Deborah, MD Congestive heart failure following upper respiratory infections, Nov, 9:41.

Keren, Andre, MD Unilateral pulmonary edema, Mar, 9:163.

Kimbiris, Demetrios, MD Coronary artery ectasia, Aug, 9:152.

Klein, Herman O., MD Verapamil-digoxin interaction: an update, Sep, 9:105.

Kostis, John B., MD Treatment of hypertension: use of pindolol, Sep, 9:53.

Kouchoukos, Nicholas T., MD The symptomatic patient after coronary bypass, Jun, 9:14.

Kupersmith, Joel, MD Arrhythmias caused by "antiarrhythmic" drugs, Jul, 9:12. Digoxin-drug interactions, Nov, 9:50.

Kurtzman, Neil A., MD Intractable edema: new treatments—and old, Dec, 9:81.

L

Lang, Roberto, MD Verapamil-digoxin interaction: an update, Sep, 9:105.

Lawless, Christine E., MD Cardiac manifestations of relapsing polychondritis, Nov, 9:56.

Lawrie, George M., MD How many bypass grafts? Sep, 9:87.

Leak, David, MD Toxoplasmosis: a cause of myocarditis, Feb, 9:149.

Leman, Robert B., MD Problems in pacemaker ECG interpretation, part I, Aug, 9:120; part II, Sep, 9:77.

Leppo, Jeffery, MD Systemic lupus erythematosus and heart disease, Jan, 9:77.

Lesch, Michael, MD Left ventricular filling pressure: noninvasive measurement, Oct, 9:31.

Lewis, Richard P., MD Prehospital coronary care: does it save lives? Jun, 9:91.

Liberthson, Richard R., MD Systemic lupus erythematosus and heart disease, Jan, 9:77.

Lichstein, Edgar, MD Postmyocardial infarction syndrome: incidence and clinical presentation, Sep, 9:172.

Lie, J.T., MD Alcoholic cardiomyopathy, Mar, 9:179.

Likoff, William, MD Controversies in cardiology, Aug, 9:180.

Lillington, Glen A., MD Anterior chest pain and acute pulmonary edema, Sep, 9:154.

M

Maddahi, Jamshid, MD Acute inferior myocardial infarction: precordial ST-segment depression, Jul, 9:173.

Madias, John E., MD Psychological distress: risk factor for acute MI, Oct, 9:141.

McKenna, William J., MD Hypertrophic cardiomyopathy: arrhythmias, Jun, 9:69.

McNally, Daniel P., MD Cardiac cause of wheezing, Oct, 9:42.

Mehl, Bernard, DPS Drug interactions with thiazide diuretics, Nov, 9:165.

Meltzer, Arthur H., MD Congestive heart failure following upper respiratory infection, Nov, 9:41.

Mikell, Frank L., MD Left ventricular thrombosis after myocardial infarction, Feb, 9:19.

Miller, Lawrence, MD Systemic lupus erythematosus and heart disease, Jan, 9:77.

Mintz, Gary S., MD Coronary artery ectasia, Aug, 9:152.

Morady, Fred, MD Disopyramide: an update, Oct, 9:18.

Morganroth, Joel, MD Acute myocardial infarction: immediate diagnosis with two-dimensional echocardiography, May, 9:71. Preventing sudden cardiac death, Aug, 9:77.

Morris, George C., Jr., MD How many bypass grafts? Sep, 9:87.

Moser, Marvin, MD The debate continues: what to do about mild hypertension? Apr, 9:14. Overinterpretation or misinterpretation of clinical trials, Sep, 9:10. What have we wrought? Dec, 9:9.

Munson, Jill T., MD Cardiac cause of wheezing, Oct, 9:42.

N

Naughton, John, MD Death rates of cardiac patients: effects of physical activity, Mar, 9:77.

Nicholson, John P., Jr., MD Hypertension treatment: use of calcium blockers, Jul, 9:108.

Northcote, Robin J., MB, ChB, MRCP A forgotten cause of aortic incompetence? Jul, 9:151.

Nostrant, Timothy T., MD Approach to atypical chest pain, Oct, 9:49.

O

Oakley, G.D.G., MRCP Athlete's heart: normality, abnormality, supernormality, Nov, 9:126.

Ockene, Ira S., MD Chest pain in the patient with normal coronary arteries, Feb, 9:83.

Ockene, Judith K., PhD Chest pain in the patient with normal coronary arteries, Feb, 9:83.

Olson, Harold G., MD Heart failure of unknown cause in the elderly, Oct, 9:57.

P

Parmley, William W., MD Acute and chronic heart failure: use of digitalis, Jan, 9:139.

Parsonnet, Victor, MD Controversies in cardiology, Aug, 9:180.

Perry, Malcolm O., MD Varicose veins and venous disease of the legs, Jul, 9:88.

Perry, Robert L., The Computing Physician, Jan, 9:22; Feb, 9:35; Mar, 9:21; Apr, 9:156; May, 9:193; Jun, 9:163; Jul, 9:184; Aug, 9:143; Sep, 9:28; Oct, 9:173; Nov, 9:172; Dec, 9:117.

Pichler, Max, MD Acute inferior myocardial infarction: precordial ST-segment depression, Jul, 9:173.

Podrid, Philip J., MD Aggravation of arrhythmias: a potential complication of therapy, Jul, 9:75.

Porter, Co-burn J., MD Dysrhythmias in pediatric patients: use of verapamil, May, 9:31.

Pryor, David B., MD Ventricular arrhythmias: prognostic importance in coronary disease, Nov, 9:146.

R

Rabkin, Simon W., MD Blood pressure in young men: prediction and prognosis, Jan, 9:105.

Rackley, Charles E., MD The symptomatic patient after coronary bypass, Jun, 9:14.

Rahimtoola, Shahbudin H., MD Controversies in cardiology, Aug, 9:180.

Rautaharju, Pentti M., MD Myocardial infarction injury score, Jun, 9:171.

Reidenberg, Marcus, MD Renal failure and congestive heart failure, Dec, 9:97.

Reisfeld, David, MD Hemolytic anemia caused by valvular heart disease, Mar, 9:74.

Rosch, Paul J., MD The Computing Physician, Jan, 9:22; Feb, 9:35; Mar, 9:21; Apr, 9:156; May, 9:193; Jun, 9:163; Jul, 9:184; Aug, 9:143; Sep, 9:28; Oct, 9:173; Nov, 9:172; Dec, 9:117.

Ruberman, William, MD Persistent risk for sudden death: ventricular arrhythmia in MI survivors, Jan, 9:33.

Rubin, Lori, MD Abdominal pain, Jun, 9:61.

Ruddy, Michael C., MD Treatment of hypertension: use of pindolol, Sep, 9:53.

Rude, Robert E., MD Right ventricular infarction: changing concepts, Jul, 9:21.

Russell, Richard O., Jr., MD The symptomatic patient after coronary bypass, Jun, 9:14.

S

Sanford, C. Fagg, MD Acute myocardial infarction: evaluation with radionuclide ventriculography, Oct, 9:121.

Savage, Daniel D., MD, PhD Chronic atrial fibrillation in the general population, Apr, 9:49.

Scanlon, Patrick J., MD Cardiac manifestations of relapsing polychondritis, Nov, 9:56.

Schiller, Nelson B., MD Carcinoid heart disease: diagnostic usefulness of echocardiography, Feb, 9:130.

Schulman, Peter, MD Cardiac cause of wheezing, Oct, 9:42.

Schneider, Ricky M., MD Early positive exercise test: implications for prognosis, Dec, 9:49.

Seaworth, John F., MD Early positive exercise test: implications for prognosis, Dec, 9:49.

Segal, Bernard L., MD Coronary artery ectasia, Aug, 9:152. Hemodynamic monitoring in acute cardiac illness, Aug, 9:92.

Selzer, Arthur, MD Preventive intervention in coronary artery disease, Jan, 9:14.

Seneff, Michael G., MD Chest pain and localized ECG changes in a 19-year-old student, Dec, 9:25

Shah, P.K., MD Acute inferior myocardial infarction: precordial ST-segment depression, Jul, 9:173.

Author Index

Sher, Ronald, MD Coronary artery ectasia, Aug, 9:152.

Siefkin, Allan D., MD Anterior chest pain and acute pulmonary edema, Sep, 9:154.

Sokoloff, Neil M., MD Preventing sudden cardiac death, Aug, 9:77.

Spann, James F., MD Hyperthyroidism or mitral valve prolapse, Oct, 9:73.

Specchia, Guiseppe, MD Variant and exertional angina: role of coronary tone, Apr, 9:71.

Spurling, Richard, MD Hemolytic anemia caused by valvular heart disease, Mar, 9:74.

Stamler, Jeremiah, MD "Mild" hypertension: risks and strategy for control, part I, Oct, 9:150; part II, Nov, 9:12.

Stamler, Rose, MA "Mild" hypertension: risks and strategy for control, part I, Oct, 9:150; part II, Nov, 9:12.

Stern, Shlomo, MD Unilateral pulmonary edema, Mar, 9:163.

Stone, Peter H., MD Exercise testing in perspective, Mar, 9:111.

Strauss, William E., MD Stable angina pectoris: use of diltiazem, Aug, 9:33.

Sullivan, Eugene D., MD Venous thrombosis of the legs: noninvasive diagnostic techniques, Aug, 9:16.

T

Tarazi, Robert C., MD Echocardiography in hemodialysis, Nov, 9:69.

Taylor, Stanley H., MD Prevention of reinfarction: use of beta blockers, Nov, 9:89.

Temkin, Lawrence P., MD Cardiomegaly of undetermined cause, Dec, 9:17.

Thadani, Udho, MBBS An unusual cause of dyspnea, weight loss, and chest pain, Aug, 9:56.

Tommaso, Carl L., MD Electrocardiographic changes induced by hyperventilation, Apr, 9:111.

Tzivoni, Dan, MD Unilateral pulmonary edema, Mar, 9:163.

W

Warren, James V., MD Hyperventilation: a diagnostic dilemma 9:127.

Weinblatt, Eve, MD Persistent risk of sudden death: ventricular arrhythmia in MI survivors, Jan, 9:33.

Continued

Nitro-Dur®
(nitroglycerin)
Transdermal Infusion System

KEY PHARMACEUTICALS, INC.
Miami, Florida 33269-0676
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Nitro-Dur®
(nitroglycerin)
Transdermal Infusion System

DESCRIPTION: The Nitro-Dur Transdermal Infusion System contains nitroglycerin in a gel-like matrix composed of glycerin, water (purified), lactose, polyvinyl alcohol, povidone and sodium citrate to provide a continuous source of the active ingredient. Nitro-Dur is available in dosage sizes 5cm², 10cm², 15cm² and 20cm², containing 26 mg, 51 mg, 77 mg and 104 mg of nitroglycerin, respectively, thereby providing a range of dosing levels of nitroglycerin. Nitro-Dur has a rated release in vivo of approximately 0.5mg/cm²/24 hours. Each unit is sealed in a polyester-foil-polyethylene laminate. The bandage portion consists of a medical grade non-woven, heat sealable, microporous tape.

CLINICAL PHARMACOLOGY: When the Nitro-Dur system is applied to the skin, nitroglycerin is absorbed continuously through the skin into the systemic circulation. This results in active drug reaching the target organs (heart, extremities) before deactivation by the liver. Nitroglycerin is a smooth muscle relaxant with vascular effects manifested predominantly by venous dilation and pooling. The major beneficial effect of nitroglycerin in angina pectoris is a reduction in myocardial oxygen consumption secondary to vascular smooth muscle relaxation with resultant reduction in cardiac preload and afterload. In recent years there has been an increasing recognition of a direct vasodilator effect of nitroglycerin on the coronary vessels.

In bioavailability studies using healthy volunteers,[1] transdermal absorption of nitroglycerin from Nitro-Dur achieved steady state venous plasma levels comparable to that of sublingual nitroglycerin and maintained these levels for 24 hours. Detectable plasma levels were attained within 30 minutes after application of the unit, and were still detectable 30 minutes after removal of the unit.

INDICATIONS AND USAGE: This drug product has been conditionally approved by the FDA for the prevention and treatment of angina pectoris due to coronary artery disease. The conditional approval reflects a determination that the drug may be marketed while further investigation of its effectiveness is undertaken. A final evaluation of the effectiveness of the product will be announced by the FDA.

CONTRAINDICATIONS: Intolerance of organic nitrate drugs, marked anemia, increased intraocular pressure or increased intracranial pressure.

WARNINGS: The Nitro-Dur system should be used under careful clinical and/or hemodynamic monitoring in patients with acute myocardial infarction or congestive heart failure.

In terminating treatment of angina patients, both the dosage and frequency of application must be gradually reduced over a period of 4 to 6 weeks in order to prevent sudden withdrawal reactions, which are characteristic of all vasodilators in the nitroglycerin class.

PRECAUTIONS: Symptoms of hypotension, such as faintness, weakness or dizziness, particularly orthostatic hypotension, may be due to overdosage. If during the course of treatment these symptoms occur, the dosage should be reduced or use of the product discontinued.

Nitro-Dur is not intended for use in the treatment of acute anginal attacks. For this purpose, occasional use of sublingual nitroglycerin may be necessary.

ADVERSE REACTIONS: Transient headache is the most common side effect, especially when higher doses of the drug are administered. Headaches should be treated with mild analgesics while continuing Nitro-Dur therapy. If headache persists, the Nitro-Dur dosage should be reduced.

Adverse reactions reported less frequently include hypotension, increased heart rate, faintness, flushing, dizziness, nausea, vomiting, and dermatitis. Except for dermatitis, these symptoms are attributed to the pharmacologic effects of nitroglycerin. However, they may be symptoms of overdosage. When they persist, the Nitro-Dur dosage should be reduced or use of the product discontinued.

HOW SUPPLIED: Nitro-Dur Transdermal Infusion System, 5cm², 10cm², 15cm² and 20cm², is available in unit dose packages of 28 and hospital packs of 100.

CAUTION: Federal law prohibits dispensing without prescription.

PATIENT INSTRUCTIONS FOR APPLICATION: Patient instructions are furnished with each unit dose package.

For complete prescribing information, please see package insert.

[1]Data on file: Key Pharmaceuticals, Inc. 07/83

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Author Index

Weld, Francis M., MD Exercise testing after acute myocardial infarction, Jan, 9:116.

Wells, John J., MD Approach to atypical chest pain, Oct, 9:49.

Wenger, Nanette K., MD Modification of coronary risks: the benefits of exercise, Nov, 9:114.

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